# Competition law enforcement in the Pharmaceutical sector

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# General prohibition of cartels

Agreements where two or more independent companies agree not to compete. This conduct can take many forms, including:

- price fixing
- market sharing
- bid-rigging
- restricting output of goods and services, etc.

Cartel prohibition applies to any form of collusion - orally, by mail, e-mail, instant messaging services and coordinated practices.

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# Prohibition of the abuse of a dominant market position

Having a dominant position in the market is not prohibited, the abuse of dominant position is.

Dominant position is the economic position in the relevant market, which enables the company:

- to significantly impede, restrict or distort competition in any relevant market for a sufficient time period
- to behave independently of its competitors, customers, suppliers and, ultimately, the final consumers

If the market share exceeds 40%, high probability of dominance (in Estonia and Lithuania presumption of dominance)

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# Criteria to establish abuse – three steps

1. Defining relevant market consisting of product and geographical market (the relevant product market can be VERY narrow! –e.g. by reference to the therapeutic indication. There have been cases where a single medicine has been regarded as constituting a separate market (e.g., an innovative medicine with no viable substitute). The product markets may be defined more broadly than within INN (International Non-proprietary Name), and more narrowly (e.g. if the route of administration is different).

2. Assessing whether the company holds dominant position in the relevant market

3. Assessing whether there has been abuse of dominant position

# Forms of abuse (examples)

- exploitative (excessive) pricing or predatory (very low) pricing aiming to drive remaining competitors out of the market
- restricting product development, product manufacturing or product sales
- unjustified discriminative treatment of trading partners;
- failure to supply a buyer without justified reason
- supplying a customer only if other products purchased that are not connected with the primary product requested
- abusive rebate systems, in particular loyalty rebates

# Competition law infringement examples in Pharmaceutical sector


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# Infringements related to restricting competition from generics or biosimilars

- Generic or biosimilar competition significantly lowers pharmaceutical prices. A study for the European Commission found that innovator drug prices drop by 40% on average after generic entry, besides generic products are often priced up to 50% lower than the original.
- To minimize the impact of generic or biosimilar competition, originator companies often implement various strategies to artificially prolong the commercial lifespan of their innovative medicines and limit competition.

# Patent misuse

Company allegedly used tactics in several European countries to extend the exclusivity of its medicine and delay the entry of competitors. This included the misuse of patent procedures, where the Company filed divisional patents with overlapping content and withdrew parent patents when challenged, creating legal uncertainty and delaying generic medicines' market entry.

(European Commission case still pending)

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# Abusive litigation

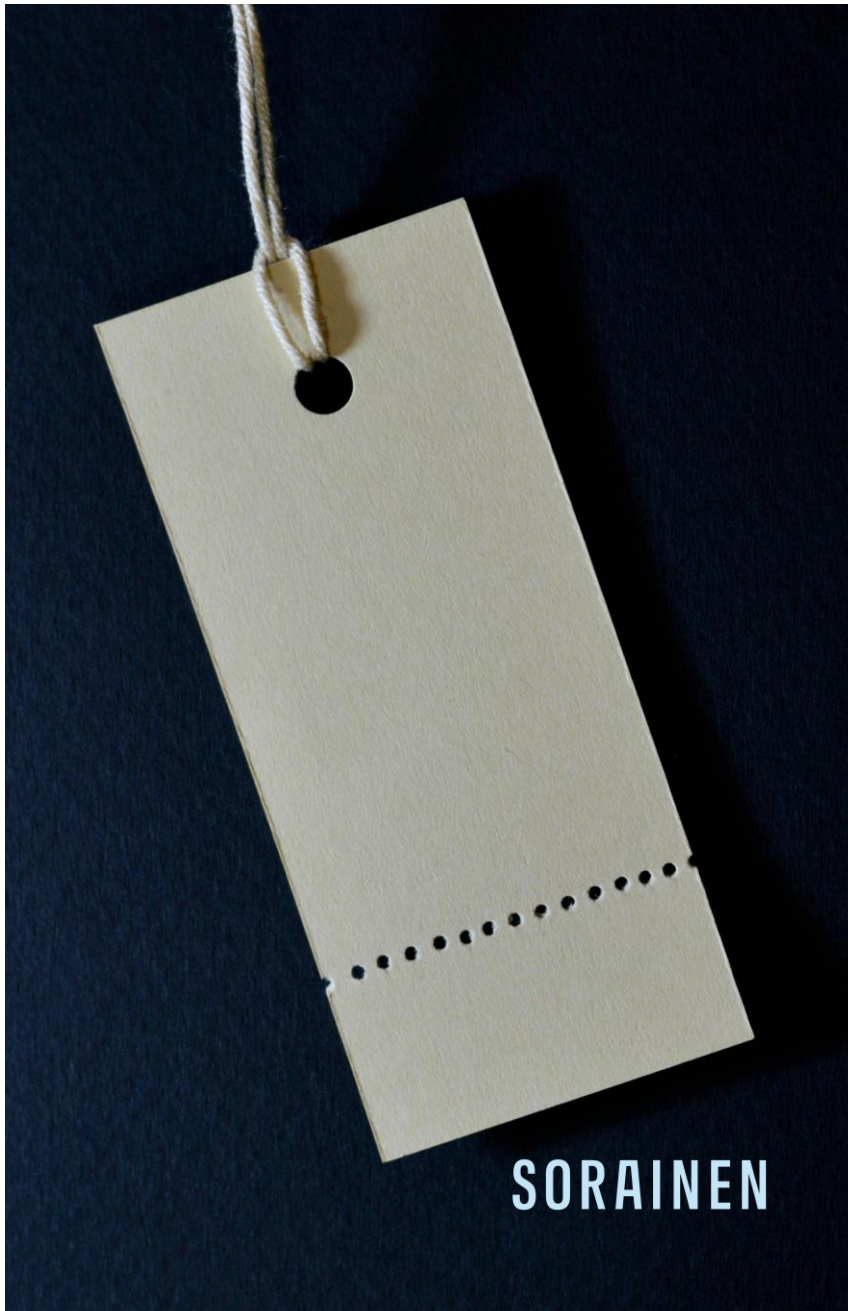
- Filing claims before a Court not to defend rights but merely to harass the opposing party as part of a plan to eliminate competition. If it can be established that the legal action by a dominant company is objectively unjustified, the practice of “abusive litigation” may constitute an abuse of dominance.
- Requesting preliminary injunction from courts not as a means to protect company’s proprietary rights but with the sole objective to halt a competitor from launching a product and thereby eliminate competition.

# Unjustified discounts

In 2019, the Dutch NCA investigated AbbVie, a former patent owner, for offering hospitals significant discounts for its medicine Humira that required continued use of Humira over cheaper biosimilars.

Discounts made it harder for biosimilar manufacturers to enter the market.

The NCA found that AbbVie's actions aimed to hinder biosimilar competition. AbbVie later removed the restrictive discount conditions, and as a result, the NCA closed its investigation.



# Excessive pricing

In 2018, the Danish Competition Council found that distributor CD Pharma abused its market dominance by raising the price of the oxytocin medicine Syntocinon by 2000% between April and October 2014.

At the time, it was the only oxytocin product with Danish marketing approval, creating a competitive disadvantage for other parties.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# Commission’s Aspen excessive pricing case

- 2021, the European Commission’s first excessive pricing investigation in the pharmaceutical sector involving Aspen Pharmacare.
- Aspen had been charging excessively high prices for six off-patent cancer medicines used to treat leukaemia and other blood cancers in Europe, when compared to the profit levels similar companies in the industry, resulting in substantial profits without justification.
- Aspen committed to reducing its prices by approximately 73% across Europe, capping these prices for ten years, and ensuring the continued supply of these medicines for at least five years. The Commission accepted these commitments, resolving the issue.

# Pay-for-delay agreements

- Pay-for-delay agreements, involving coordination between competitors, fall under Article 101 TFEU and similar national competition laws. They have the object of restricting competition and may also constitute an abuse of a dominant position if exercised by a dominant company.
- Involve deals between originator and generic companies, where the first delays its market entry in exchange for significant benefits from the originator.
- Benefit both parties. The originator gains extra profits from extended market exclusivity, and the generic company receives a share of these profits without entering the market.

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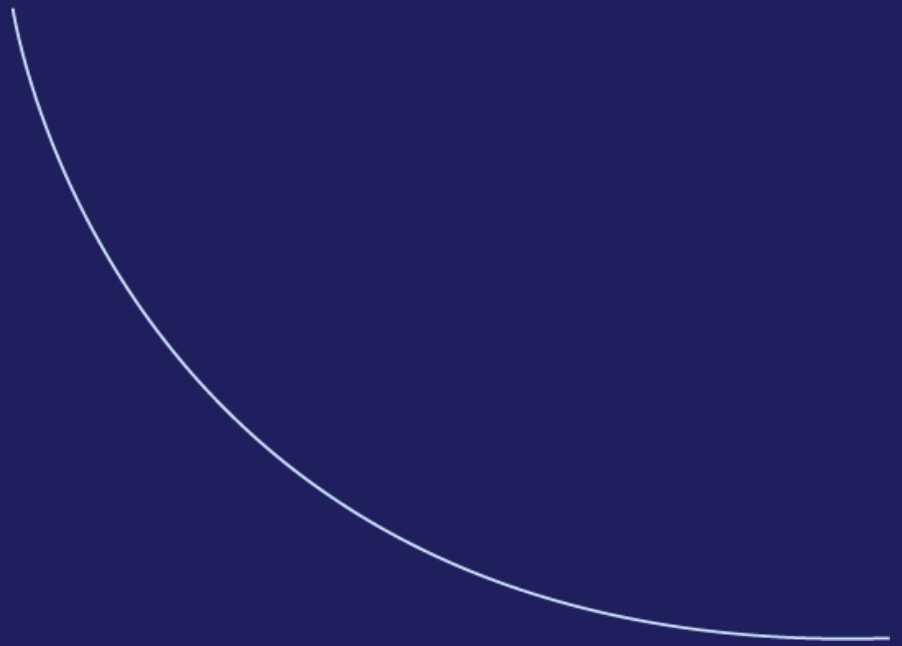
# Disparagement



- Disparagement in the pharmaceutical industry occurs when established companies undermine competitors, particularly new entrants, to hinder rolling-out of their products.
- This can involve e.g., spreading false or misleading information about the competitors' products. Such actions can mislead healthcare providers and patients, stifle innovation, and harm competition.

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# Legal consequences for breaching competition laws

- Monetary fines can reach from thousands to millions of EUR. In the EU, the fine would be a maximum of 10% of the group's worldwide annual turnover.
- The agreements concluded in violation of competition law regulations are legally void and invalid
- Injured parties are generally entitled to claim for damages
- Many competition laws offer leniency programs that provide reduced penalties or even full immunity from fines to infringers who report a cartel to authorities and supply enough evidence. Increasingly, companies are using these programs to avoid potential cartel penalties, leading to a significant rise in the detection of cartel law violations.

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Thank you!


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